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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/775,677 | 02/05/2001 | Jan Otto Solem | JM-050 CIP | 3473 |

7590

06/29/2004

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| EXAMINER |
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CHATTOPADHYAY, URMJ

| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|------------------------------|--|
| Office Action Summary | Application No. 09/775,677 | Applicant(s) SOLEM ET AL. | |
| | Examiner Urmi Chattopadhyay | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 22, 25-27, 29, 30, 32-40 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-17, 22, 25-27, 30, 32-40 and 74 is/are allowed.
- 6) ☒ Claim(s) 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 3/11/04 has been entered. Claims 1-13, 24, 31 and 73 have been canceled. The claims currently pending are 14-17, 22, 25-27, 29, 30, 32-40 and 74.
2. The amendment filed 3/11/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the new sentence added to the end of the paragraph beginning on page 16, line 22 contains new matter. There is no support in the original specification, claims or drawings or in the amended Figure 13 for the wires 26, 27 being *secured* to the stents. While there is support for the stents being "connected" by the wires, the wires are not necessarily *secured*, defined as "fastened" or "fixed", to them. Additionally, there is no support for the specific method steps of the wires being "severed and removed". Just because portions of the wires 26, 27 are no longer present in the coronary sinus, as shown in Figure 13, it does not necessarily mean that they were severed and removed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Terminal Disclaimer

3. The terminal disclaimer filed on 3/11/04 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,210,432 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Art Unit: 3738

Drawings

4. The parent case 09/345,475 was ordered, and the Certificate of Correction and original drawings filed were carefully reviewed. The examiner concludes the changes to Figure 13 shown the Replacement Sheet filed 3/11/04 in the current application are fully supported, and therefore, are approved.

Election/Restrictions

5. Claims 22 and 40 are generic and allowable. Accordingly, the restriction requirement as to the encompassed species is hereby withdrawn and claims 25-27, 29 and 32-36, directed to the species 1-8 of Figures 1-18 are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim.

In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 3738

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 29 was first presented in a preliminary amendment filed on 10/19/01, which is after the application filing date of 2/5/01. The limitation of the device further comprising a lock for retaining the elongate body in the second configuration at least in part within the coronary sinus is therefore considered new matter. Neither the original specification nor the amended Figure 13 discloses "a lock". Absent an explicit, clear, deliberate and precise definition of "lock" in the specification, "lock" is given its plain meaning. That plain meaning is "a device used, as on a door, to close, hold or secure and operated by various means, as a key or combination" (defined in Webster's II New Riverside University Dictionary). The mere mentioning of the stents being "connected" by wires in the specification, and the mere showing of the wires between the stents in amended Figure 13 are not sufficient to provide support for a lock as defined, specifically one that is capable of retaining the elongate body in the second configuration at least in part within the coronary sinus. The plain meaning of "lock" is more specific than the plain meaning of "connection". In other words, the wires could be connected to the stents using other than a lock. Limiting the connection to a lock in claim 29 without doing so in the specification is therefore, considered new matter. See MPEP 2163.05 II.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 29 is rejected under 35 U.S.C. 102(e) as being anticipated by Langberg et al. (USPN 6,402,781 as cited in applicant's IDS).

Claim 29 was first presented in a preliminary amendment filed on 10/19/01, which is after the application filing date of 2/5/01. Because claim 29 contains limitations that are considered new matter, it will not receive benefit of the filing date of the parent application, 09/345,475, but will have an effective filing date of the application filing date of 2/5/01.

Langberg discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 29. See Figure 2 for an elongate body (40) extending between a proximal end (42) and a distal end (44), and that is adjustable between a first configuration having a first shape such that the body is adapted to be delivered within a coronary sinus (22) and a second configuration having a second shape such that the body is adapted to exert a force from within the coronary sinus (22) onto and remodel the mitral valve annulus when adjusted to the second configuration. The device further comprises a lock (70) for retaining the elongate body (40) in the second configuration at least in part within the coronary sinus. See column 8, lines 52-58.

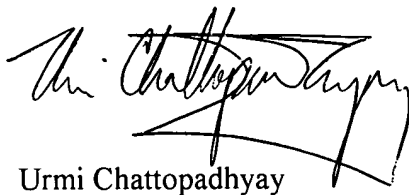
Art Unit: 3738

Allowable Subject Matter

10. Claims 14-17, 22, 25-27, 30, 32-40 and 74 are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella
Primary Examiner